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EXAMINER

RAMIREZ, DELIA M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1652

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,781

Applicant(s)

SOULARD, PATRICIA

Examiner

Delia M. Ramirez

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-78 is/are pending in the application.
- 4a) Of the above claim(s) 12-18,20-52 and 54-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11,19,53 and 68-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Claims 1-2 and 4-78 are pending.

Applicant's amendment of claims 1-2, 4-11, 19, 53, cancellation of claim 3, and addition of claims 68-78 in a communication filed on 12/17/2004 is acknowledged.

Applicants request reconsideration of the finality of the restriction requirement on the grounds that (1) examination of the polypeptides of SEQ ID NO: 1-3 would not impose an undue burden of search since there is a high degree of homology among these polypeptides, and (2) the number of sequences to be searched is a reasonable number according to MPEP 803.4. These arguments have been fully considered but are not deemed persuasive. The guidelines set forth in M.P.E.P. § 803.04 clearly indicate that *up to (not at least)* 10 independent and distinct nucleotide/polypeptide sequences can be examined in a single application. Therefore, the number of nucleotide/polypeptide sequences to be examined in one single application can vary from 1 to 10. However, searching more than one polypeptide sequence per application will place an undue burden upon the Examiner and the Office since the search of sequences is not co-extensive. It is noted that even if the level of structural similarity among the polypeptides of SEQ ID NO: 1-3 is high, the Examiner has to conduct a sequence search for each one of the different sequence identifiers recited. While the argument can be made that a search of a genus of homologs of the polypeptide of SEQ ID NO: 1 would disclose specific species within that genus, in the instant case, the claims are also directed to a genus of homologs of specific species (i.e., SEQ ID NO: 2-3; claim 19). Since a genus of homologs of the polypeptide of SEQ ID NO: 1 would not encompass all the species of a genus of homologs of the polypeptide of SEQ ID NO: 2 or 3, a search of the genus of homologs of the polypeptide of SEQ ID NO: 1 is not co-extensive to the additional genera. Furthermore, sequence searches involve several databases and not just a BLAST search as indicated by Applicants. In addition, since a sequence is just an additional characteristic of a protein, a comprehensive search of each

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of the polypeptides of SEQ ID NO: 1-3 would also require a patented/non-patented literature search for each one of the polypeptides of SEQ ID NO: 1-3. Thus, an undue burden would be imposed on the Office if all these polypeptides were to be examined. As previously indicated, the requirement is deemed proper and therefore is made FINAL.

This application contains claims 12-18, 20-52, 54-67 drawn to an invention non-elected with traverse in a communication filed 5/7/2004. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

1. The specification remains objected for not complying with sequence rules. Specifically, Figure 1 discloses sequences, no sequence identifiers are shown in Figure 1, and the Brief Description of the Drawings does not refer to a specific sequence identifier in regard to Figure 1. Applicants argue that no sequence identifier is included in Figure 1 as the sequences depicted therein are longer than the sequences referred to in any one of SEQ ID NO: 1-3. This argument is not found persuasive. The requirements set forth in 37 CFR 1.821(a)-(c) clearly indicate that sequences disclosed in the specification which are four or more amino acids in length or 10 or more nucleotides in length shall conform to the requirements of §§1.821-1.825. As such, since the Figures are part of the disclosure and the sequences listed in Figure 1 are longer than 4 amino acids in length, they are subject to the requirements of §§1.821-1.825. It is suggested that if these sequences have been included in the Sequence Listing and have a sequence identifier, at least the Brief Description of the Drawings should be amended to indicate which sequence identifier correspond to each of the sequences listed in the Figure. If these sequences do not have a sequence identifier, they may be included in a new sequence listing as long as no new matter is included. Appropriate correction is required.

Claim Objections

2. Claims 4-9, 19, 53 and 77-78 are partially drawn to non-elected inventions. Examination of such claims will be restricted to the subject matter elected, which in the instant case is the polypeptide of SEQ ID NO: 1. Applicants are requested to amend the claims accordingly in response to this Office Action.
3. Claims 1-2, 19, 68-78 are objected to due to the following informalities: the terms "7", 7A1" and "7A2" have been placed next to the term "phosphodiesterase" without leaving an space between them (e.g., phosphodiesterase7). Appropriate correction is required.
4. Claims 2, 68-69 are objected to due to the recitation of "a functional catalytic domain of the endogenous full length phosphodiesterase 7 protein" since these claims depends upon claim 1, which already requires this functional catalytic domain. Appropriate correction is required.
5. Claims 68-69 are objected to due to the recitation of "mutated [truncated] regulatory domain". The term is deemed redundant in view of the fact that claim 1 requires the regulatory domain to be inactive. If the term is intended to limit the method by which the inactivation occurs, it is suggested the claims be amended to recite "inactive regulatory domain of the endogenous full length..., wherein said regulatory domain is inactive due to a mutation [truncation]", or similar. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 1-2, 4-11, 19, 53 remain rejected and new claims 68-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by amendment.

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8. Claims 4-9 are indefinite due to the recitation of “the isolated...polypeptide according to claim 78 which comprises the amino acid sequence beginning at the amino acid residue in position X and ending at the amino acid residue in position Y of SEQ ID NO: 1” for the following reasons. Claim 78 is directed to a polypeptide according to claim 19 wherein the polypeptide comprises SEQ ID NO: 1. Thus, a polypeptide comprising a fragment of SEQ ID NO: 1 is broader in scope than one comprising SEQ ID NO: 1. As such, claims 4-9 are not further limiting claim 78. For examination purposes, it will be assumed that claims 4-9 recite “claim 19” instead of “claim 78”. Correction is required.

9. Claims 1, 19, 53, 70-76 (claims 2, 4-11, 68-77) are indefinite in the recitation of “higher phosphodiesterase catalytic activity than the phosphodiesterase catalytic activity of an endogenous full length phosphodiesterase 7A1 protein or phosphodiesterase 7A2 protein”, “inhibits phosphodiesterase 7A activity”, and “phosphodiesterase catalytic activity ..than the phosphodiesterase catalytic activity of an endogenous full length phosphodiesterase 7A1 protein or phosphodiesterase 7A2 protein” for the following reasons. While the art recognizes phosphodiesterase 7 proteins to be a family of enzymes within the superfamily of phosphodiesterases (PDE) which can be distinguished from other families by their substrate specificity, tissue expression, localization, structure, and sensitivity to PDE inhibitors, there are no specific identifying characteristics disclosed which would allow one of skill in the art to determine if a protein from any source is a PDE 7A, PDE 7A1 or PDE 7A2 protein. Thus, the mere recitation of “phosphodiesterase 7A1”, “phosphodiesterase 7A “, or “phosphodiesterase 7A2” does not allow one of skill in the art to determine which specific enzymatic activity is encompassed by the terms.

In addition, since the term “an endogenous full length ...protein” encompasses a genus of proteins, determining whether a polypeptide meets the recited functional limitation is impossible as the basis for comparison is variable. For example, if a mutant protein’s phosphodiesterase catalytic activity is compared to that of two species of the genus of endogenous phosphodiesterase proteins recited, each one having different phosphodiesterase catalytic activity against the same substrate, the same mutant

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protein can have a higher phosphodiesterase catalytic activity or meet the numerical limitation recited regarding phosphodiesterase catalytic (i.e. X fold higher than) activity with respect to one of the species of endogenous phosphodiesterase proteins, and at the same time, have a lower phosphodiesterase catalytic activity or fail to meet the numerical limitation recited regarding phosphodiesterase catalytic activity with respect to the other species of phosphodiesterase 7 proteins.

It is noted that if the intended activities are those of specific polypeptides having a defined amino acid sequence, the claims may be amended to indicate which specific polypeptide is associated with the activities recited. For example, if the polypeptide of SEQ ID NO: X has been defined as a phosphodiesterase 7A1 and the polypeptide of SEQ ID NO: Y has been defined as a phosphodiesterase 7A2, the claim may be amended to recite "higher phosphodiesterase catalytic activity than the phosphodiesterase catalytic activity of the endogenous full length phosphodiesterase 7A1 protein of SEQ ID NO: X or phosphodiesterase 7A2 protein of SEQ ID NO: Y". For examination purposes, no patentable weight will be given to the terms "higher phosphodiesterase catalytic activity than the phosphodiesterase catalytic activity of an endogenous full length phosphodiesterase 7A1 protein or phosphodiesterase 7A2 protein", and "phosphodiesterase catalytic activity ..fold higher than the phosphodiesterase catalytic activity of an endogenous full length phosphodiesterase 7A1 protein or phosphodiesterase 7A2 protein". The term "inhibits phosphodiesterase 7A activity" will be interpreted as "inhibits phosphodiesterase 7 activity". The terms "phosphodiesterase 7A1", "phosphodiesterase 7A ", and "phosphodiesterase 7A2" will be interpreted as "phosphodiesterase 7 ". Claims 71-76 will be considered duplicates of the claims from which they depend (68 or 69). Correction is required.

10. Claims 71-76 are indefinite in the recitation of "at least about" because the term "about" can be interpreted as "less than" whereas the term "at least" is synonym of "no less than", thus the term "at least about" is contradictory. Correction is required.

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11. Claims 2, 77-78 (claims 4-11 dependent thereon) are indefinite in the recitation of “homologous polypeptide thereof” as one cannot determine if the term “thereof” refers to the isolated or purified mutant polypeptide or the full length phosphodiesterase 7 protein. For examination purposes, it will be assumed it refers to the isolated or purified mutant polypeptide. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 2, 4-9, 53 remain rejected and claims 10-11 (amended), 77-78 (new) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection as it relates to claims 10-11 and 77-78 is necessitated by amendment.

14. Applicants argue that the specification teaches the generation of deletion mutants of the PDE7A protein using PCR. According to Applicants, the information regarding the structure of these mutants and their functionality provide a correlation between structure and function and provide a structure for other phosphodiesterases, structural homologs of a polypeptide comprising at least 312 amino acids of the polypeptide of SEQ ID NO: 1, and any phosphodiesterase having the recited degree of enzymatic activity.

15. Applicant’s arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 2, 4-9, 53 or avoid the rejection of claims 10-11, 77-78. The term “homologous polypeptide thereof” as recited in the instant claims does not convey any particular limitation in regard to

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the level of structural homology or function. As such, claim 2 is directed in part to a genus of homologs of any function and structure of the mutant polypeptide of claim 1 as interpreted. Claims 10-11 are directed in part to a genus of homologs of any function and structure of the mutant polypeptide of claim 2. Claims 4-9 are directed in part to a genus of homologs of any function and structure of mutant polypeptides comprising specific amino acid fragments of the polypeptide of SEQ ID NO: 1. Claims 77-78 are directed in part to a genus of homologs of any function and structure of polypeptides comprising all of SEQ ID NO: 1 or 312 amino acids of SEQ ID NO: 1. Claim 53 is directed in part to a kit comprising any of the genus of homologs of claims 2, 4-9. See Claim Rejections under 35 USC 112, second paragraph for claim interpretation. Since there is no recited structural limitations or functional limitations for these homologs, the genus of polypeptides claimed is an extremely large, functionally and structurally variable genus. As previously indicated, while a sufficient written description of a genus of polypeptides may be achieved by a recitation of a representative number of polypeptides defined by their amino acid sequence or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus, in the instant case, there is no structural feature which is representative of all members of the genus. Thus, one cannot reasonably conclude that the claimed genus is adequately described.

16. Claims 1-2, 4-11, 19, 53 remain rejected and new claims 68-78 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO: 1, does not reasonably provide enablement for (1) any homolog of the polypeptide of SEQ ID NO: 1 having any structure or function, (2) any homolog of a polypeptide comprising specific fragments of the polypeptide of SEQ ID NO: 1, or (3) a polypeptide having at least 90% sequence identity to the polypeptide of SEQ ID NO: 1 having phosphodiesterase 7 activity and comprising any inactive regulatory domain. The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is necessitated by amendment.

17. Applicants argue that the claims have been amended such that they are now limited to polypeptides having at least 90% sequence identity to either human, mouse, or rat PDE7 proteins. Also, Applicants submit that the specification teaches the critical structural elements required to provide the desired function and that a correlation between structure and function of PDE7A mutants have been provided. Thus, no undue experimentation is required.

18. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 1-2, 4-11, 19, 53 or avoid the rejection of new claims 68-78. The Examiner acknowledges the amendments to the claims and the teachings of the specification but disagrees with Applicant's contention that the claimed invention is fully enabled by the teachings of the specification. As previously discussed in regard to the written description rejection, claims 2, 4-11, 53, 77-78 are directed to a genus of homologs of any structure and function due to the recitation of "homologs thereof". See above for discussion of the scope of the instant claims. Since the specification fails to teach the function and structure of all these homologs, or a structure/function correlation between the polypeptide of SEQ ID NO: 1 and the required enzymatic function, one of skill in the art would have to go through the burden of undue experimentation in order to make homologs as recited which display the desired enzymatic characteristics, and/or determine the function of all the structural homologs as claimed which do not display the desired activity. In addition, the specification fails to disclose which are the structural elements in the polypeptide of SEQ ID NO: 1 that can be modified and which ones can be conserved to create a 90% sequence identical homolog having the recited enzymatic characteristics. As known in the art and previously discussed in the Non Final Action, the art teaches several examples wherein even small amino acid substitutions substitution can result in changes in enzymatic activity. See particularly the teachings of Witkowski et al. (Biochemistry 38:11643-11650, 1999). Furthermore, while claims 1 and 19

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require the presence of any inactive regulatory domain (from any protein and having any type of regulatory activity), the specification only teaches polypeptides having an inactive regulatory domain wherein said regulatory domain inhibits phosphodiesterase activity. No additional inactive regulatory domains are taught by the specification. Thus, it would require undue experimentation to create structural homologs as recited which comprise any inactive regulatory domain and determine which ones display the desired enzymatic activity. Therefore, one of skill in the art cannot reasonably conclude that the specification enables the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

19. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

20. Claims 2, 4-11, and 53 were rejected under 35 U.S.C. 102(b) and new claims 77-78 are rejected as being anticipated by Han et al. (J. Biol. Chem. 272(26):16152-16157, 1997). This rejection has been discussed at length in the Non Final Action mailed on 6/17/2004. It is now applied to amended claims 2, 4-11, 53 and new claims 77-78 for the reasons of record and those set forth below.

21. Applicants argue that the claims as amended are now directed to polypeptides at least 30 amino acids shorter at the amino terminus in comparison to the sequence which Han et al. discloses.

Furthermore, according to Applicants, Han et al. does not teach the claimed activity.

22. Applicant's arguments have been fully considered but are not deemed persuasive. The Examiner agrees that the splice variant of Han et al. does not have an inactive regulatory domain based on the teachings of the specification, page 27, lines 14-16, where it is indicated that this regulatory region encompasses amino acids 31-100 of the full length PDE7A (482 amino acids). Since the splice variant of Han et al. comprises amino acids 26-482 of the full length PDE7A, according to the specification, it contains an intact/active regulatory region. However, the instant claims are directed in part to homologs

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of any structure and function of the polypeptide of SEQ ID NO: 1 due to the recitation of "homologs thereof". See above for discussion of the scope of these claims. Since any polypeptide sharing at least one amino acid with the polypeptide of SEQ ID NO: 1 can be considered a homolog of the polypeptide of SEQ ID NO: 1, the polypeptide of Han et al. is deemed to be a homolog of the polypeptide of SEQ ID NO: 1 as well as of the claimed polypeptides, thus it anticipates claims 2, 4-11, 77-78 as written. As previously indicated, Han et al. teaches how to perform phosphodiesterase assays on the splice variant as well as the measurement of PDE activity in the presence of the inhibitor rolipram (page 16153, right column, PDE assays). Since claim 53 is directed to a kit to screen for compounds that inhibit PDE7 activity wherein said kit comprises the homologs of claims 2, 4-9 as well as the reagents required to measure PDE activity, the teachings of Han et al. also anticipate the instant claim as written.

23. Claims 1-2, 4-11, 19 remain rejected and new claims 68-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffmann et al. (Cell Biochem. Biophys 28:103-113, 1998; Swiss Prot Accession Number O08593). This rejection has been discussed at length in the Non Final Action mailed on 6/17/2004. It is now applied to amended claims 1-2, 4-11, 19 and new claims 77-78 for the reasons of record and those set forth below.

24. Applicants argue that Hoffmann et al. does not teach any of SEQ ID NO: 1-3 and that the polypeptide of Hoffmann et al. is 433 amino acids long whereas SEQ ID NO: 1-3 are 426 amino acids long. Furthermore, Applicants submit that Hoffmann et al. does not teach the claimed activity.

25. Applicant's arguments have been fully considered but are not deemed persuasive. It is noted that claim 53 was inadvertently included in the list of rejected claims. Thus, this rejection is hereby withdrawn in regard to claim 53. Hoffmann et al. discloses a fragment of the rat PDE7 protein having 426 amino acids as shown in the previously submitted alignment (Swiss Prot Accession Number O08593; 1998). The polypeptide of Hoffman et al. as shown in Swiss Prot Accession Number O08593 lacks the

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first 56 amino acids of the full length PDE7A. Therefore, it has a truncated regulatory domain which would be inactive based on the teachings of the specification previously discussed. The polypeptide of Hoffman et al. is 94.1% sequence identical to the polypeptide of SEQ ID NO: 1. Claims 1-2, 19, 68-76 are directed in part to a polypeptide having 426 amino acids, and having a functional catalytic domain of an endogenous phosphodiesterase 7 protein and a truncated regulatory domain of an endogenous phosphodiesterase 7 protein, wherein the polypeptide is at least 90% sequence identical to SEQ ID NO: 1, and wherein said polypeptide has phosphodiesterase 7 activity. See Claim Rejections under 35 USC 112, second paragraph for claim interpretation. Claims 4-11, 77-78 as indicated previously are directed to homologs of the polypeptide of SEQ ID NO: 1 having any structure and function. Therefore, the polypeptide of Hoffmann et al. anticipates the instant claims as written.

Claim Rejections - 35 USC § 103

26. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

27. Claim 53 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffmann et al. (Cell Biochem Biophys 28:103-113, 1998; Swiss Prot Accession Number O08593) in view of Han et al. (J. Biol. Chem. 272(26):16152-16157, 1997). This rejection has been discussed at length in the Non Final Action mailed on 6/17/2004. It is now applied to amended claim 53 for the reasons of record and those set forth below.

28. Applicants argue that Hoffmann et al. neither teaches nor provides motivation to make the claimed kit. Also, Applicants argue that Hoffmann et al. does not teach the polypeptide of claims 1-2, 4-9, 19 or 68-78. Therefore, the claimed kit is not obvious over these references. In addition, Applicants submit that neither Hoffmann nor Han teach the claimed activity. Thus, one of skill in the art would not have been motivated to make the claimed kit.

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29. Applicant's arguments have been fully considered but are not deemed persuasive. As indicated above, the teachings of Hoffmann et al. anticipate claims 1-2, 4-9, 68-76. The kit of claim 53 requires the polypeptides of claims 1-2, 4-9, or 68-76. Therefore, for the reasons extensively discussed in the Non Final Action mailed on 6/17/2004, the teachings of Hoffmann et al. and Han et al. render the instant kit obvious over the prior art of record. Hoffmann et al. teach a motivation, i.e. testing different inhibitors for further characterization of the PDE7 and Han et al. teach that there is a reasonable expectation of success at making the kit. In view of the teachings of the prior art, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

30. No claim is in condition for allowance.

31. Applicant's amendment of claims 1-2, 4-11, 19, 53 and addition of claims 68-78 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

32. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (571) 273-8300. The faxing of such papers must conform with the

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notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

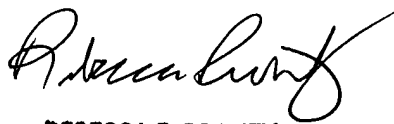
33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
June 20, 2005


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1602